FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, Maryland July 19, 2016

DRAFT MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Jennifer Shepherd, RPh

Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE MEMBER (Voting)

Michael Bigby, MD

(Chairperson)

Associate Professor of Dermatology Harvard Medical School and Beth Israel Deaconess Medical Center Boston, Massachusetts

Ken Katz, MD, MSc, MCSE

Dermatologist Kaiser Permanente San Francisco, California

DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Marla B. Sultan, MD, MBA

(Industry Representative)

Global Clinical Lead, Clinical Development

Pfizer, Inc.

New York, New York

TEMPORARY MEMBERS (Voting)

Bonnie H. Arkus, RN

(Consumer Representative)

President, Women's Heart Foundation Hamilton Township, New Jersey

Warren B. Bilker, PhD

Professor of Biostatistics

Department of Biostatistics and Epidemiology

Perelman School of Medicine University of Pennsylvania Philadelphia, Pennsylvania

Michael J. Blaha, MD, MPH

Director of Clinical Research and Assistant Professor Johns Hopkins Ciccarone Center for Prevention of Heart Disease

Baltimore, Maryland

Erica Brittain, PhD

Mathematical Statistician and Deputy Branch Chief Biostatistics Research Branch

National Institute of Allergy and Infectious Disease (NIAID)

National Institutes of Health (NIH)

Bethesda, Maryland

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DRAFT MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

John J. DiGiovanna, MD

Senior Research Physician DNA Repair Section Dermatology Branch Center for Cancer Research National Cancer Institute, NIH Bethesda, Maryland

Michael R. Irwin, MD

Cousins Distinguished Professor of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine at UCLA
Distinguished Professor of Psychology, UCLA
College of Letters and Sciences
Director, Cousins Center for
Psychoneuroimmunology, Semel Institute for
Neuroscience
Director, Mindful Awareness Research Center
Los Angeles, California

Stephen R. Marder, MD

Professor and Director, Section on Psychosis Semel Institute for Neuroscience at UCLA Los Angeles, California

Matthew V. Rudorfer, MD

Chief, Somatic Treatments and Psychopharmacology Program Division of Services and Intervention Research National Institute of Mental Health (NIMH), NIH Bethesda, Maryland

Ming T. Tan, PhD

Professor & Chair Dept. of Biostatistics, Bioinformatics & Biomathematics Georgetown University Washington, District of Columbia

Lynn A. Drake, MD

Lecturer Harvard Medical School Department of Dermatology Massachusetts General Hospital Boston, Massachusetts

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Elaine H. Morrato, DrPH, MPH

Associate Dean for Public Health Practice Associate Professor Department of Health Systems, Management and Policy Colorado School of Public Health University of Colorado Anschutz Medical Campus Aurora, Colorado

Elizabeth Smith

(Patient Representative) Burke, Virginia

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DRAFT MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Consuelo Walss-Bass, PhD

Associate Professor Department of Psychiatry and Behavioral Sciences McGovern Medical School University of Texas Health Science Center at Houston Houston, Texas

Julie M. Zito, PhD

Professor of Pharmacy and Psychiatry University of Maryland, Baltimore Pharmaceutical Health Services Department Baltimore, Maryland

David D. Waters, MD

Professor Emeritus,
Division of Cardiology,
San Francisco General Hospital,
Department of Medicine,
University of California, San Francisco
San Francisco, California

FDA PARTICIPANTS (Non-Voting)

Amy Egan, MD

Deputy Director Office of Drug Evaluation III (ODE III) Office of New Drugs (OND), CDER, FDA

Gary Chiang, MD, MPH

Medical Officer DDDP, ODE III, OND, CDER, FDA

Kendall A. Marcus, MD

Director Division of Dermatology and Dental Products (DDDP) ODE III, OND, CDER, FDA

Cynthia L. LaCivita, PharmD

Director

Division of Risk Management (DRISK), Office of Medication Error Prevention and Risk Management, Office of Surveillance and Epidemiology (OSE), CDER, FDA

Simone P. Pinheiro, ScD, MSc

Deputy Director (Acting)
Division of Epidemiology I, Office of
Pharmacovigilance and Epidemiology (OPE), OSE,
CDER, FDA